DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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WARNING LETTER
NWE-28-00W

VIA FEDERAL EXPRESS

April 26, 2000

Paul Cummings
President
CCL Custom Manufacturing, Inc.
6133 North River Road
Suite 800
Rosemont, IL 60018

Dear Mr. Cummings:

During an inspection of your drug manufacturing facility, CCL Custom Manufacturing, Inc. located at 35 Martin Street, Cumberland, RI on March 13 through 23, 2000 our Investigator found significant deviations from the Good Manufacturing Practices for Finished Pharmaceuticals (Title 21 Code of Federal Regulations, Parts 210 and 211). Such deviations cause drugs such as [redacted] Spray Powder, [redacted] Antifungal Powder, [redacted] Antifungal Powder and [redacted] manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act). The violations observed during our inspection include, but are not limited to, the following:

1. Failure to perform a thorough investigation, including conclusions and follow-up, when your drug products do not meet their finished product specifications. For example, on at least sixteen occasions your firm reviewed finished product test results that were out of specification (OOS). There is no documentation available to demonstrate that an appropriate investigation is conducted to determine the root cause of these batch failures.

specification (OOS). There is no documentation available to demonstrate that an appropriate investigation is conducted to determine the root cause of these batch failures.

2. Failure to have and follow written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. For example, your firm has not completed validation for the manufacture of [redacted] Aloe Vera and [redacted] Liquid. Also, your records indicate that you have reworked batches on a number of different drug products. There was no documentation available to indicate that these rework procedures have been validated.

3. Failure to follow your own SOP, "04-003 – Retesting OOS Results" for the investigation of out of specification results for your drug products.

4. Failure to establish procedures for the cleaning of your drug manufacturing equipment that include a description, in sufficient detail, of the methods, equipment, and materials used to assure that the equipment is adequately cleaned. For example, there was no data available to demonstrate that your filling nozzles are cleaned properly.

5. Failure to have written master production records that include complete manufacturing and control instructions, and sampling and testing procedures. For example, your drug manufacturing records do not include mixer settings (speeds) to assure uniformity from batch to batch.

You should take prompt action to correct all of the violations at your firm. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions may include seizure and or injunction under the Federal Food, Drug, and Cosmetic Act.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the above violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

We acknowledge your letter dated April 12, 2000 which was in response to the FDA 483 that was issued to your firm at the close of our inspection. At your request, we have also arranged a meeting for May 3, 2000 at 11:00 am at our district office to discuss the corrections you are implementing at your facility to bring yourselves into compliance. In your response to this Warning Letter, please advise us of your status with respect to the planned corrections at your facility.

The deficiencies identified in this letter are not intended to be an all-inclusive list of the deficiencies at your facility. As President, it is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

David K. Elder
Acting District Director
New England District Office

cc:

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